



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

OPPTS/OPP/RD/TRB/PRODUCT CHEMISTRY TEAM

WASHINGTON, D.C. 20460

DATE: 26/NOV/2001

SUBJECT: **PRODUCT CHEMISTRY REVIEW OF MP [] EP [X]**

DP BARCODE No.: D278910

REG./File Symbol No.: 279-GEUR

PRODUCT NAME: Aim 2EC

COMPANY: FMC Corp Agricultural Products Group

SB
12-4-01

FROM: Linda L. Kutney, Chemist
Product Chemistry Team
Technical Review Branch/RD (7505C)

Linda L Kutney
11/26/01

TO: Joanne Miller/Dianne Morgan PM 23
Herbicide Branch/RD(7505C)

INTRODUCTION

FMC previously submitted two new herbicide uses for their technical, carfentrazone-ethyl (Reg. No. 279-3181, 90%), in new products Aim 2 EC and Aim 2 EW, (279-GEUR and 279-GEUE, respectively). Food crops include uses on corn, sorghum, rice, soybeans, wheat, barley, oats, etc.

This submission includes FMC's responses to TRB's 10/12/01 review concerning Aim 2 EC, Reg. No. 279-GEUR, also referred to as Carfentrazone-ethyl 240 g/l EC and as "Carfentrazone-ethyl 240 EC."

A revised label for Aim 2EC was pin-punched by the Agency on 10/22/01; a revised CSF for Aim 2EC was dated 10/19/01. Two new CSFs, dated 10/15/01, were submitted for inert compounds used within Aim 2EC (See Confidential Appendix).

10/12/01 Deficiency

The Reg. No. on the CSF, in box 4, must read "279-GEUR."

FMC Response and Current TRB Conclusion

Box 4 of the CSF for Aim 2EC, now reads "279-GEUR." This deficiency is resolved.

10/12/01 Deficiency

Labels previously proposed for Aim 2 EC contained an incorrect values for the % Carfentrazone-ethyl, which did not agree with the nominal concentration of Carfentrazone-ethyl on the 6/15/01 CSF.

FMC Response and Current TRB Conclusion

FMC has now adequately addressed this issue. The proposed label and the CSF now indicate the label claim is 22.3% Carfentrazone-ethyl, with 77.7% inert ingredients. The nominal concentration of the ai on the CSF is now identical to the label claim percentage.

10/12/01 Deficiency

FMC was required to include the label warnings, "Contains Petroleum Distillates" and "Flammable."

FMC Response and Current TRB Conclusion

FMC has complied with these requirement, but TRB has deferred to the PM as to the size of the two warning statements. This deficiency is resolved.

10/12/01 Deficiencies

Data corresponding to guideline reference 830.155 (chemical identity) are still required. The data submitted corresponding to the guideline reference 830.1550(Product Identity)and 830.1750 (Certified limits) do not satisfy the data requirements of 40CFR§158.155 and 158.175 respectively, since some of the inert ingredients used in the formulation are not cleared by the Agency.

AND

Deficiencies concerning the CSFs for the inerts must be addressed.

AND

Trade name, CAS No., complete chemical composition and percentages of each component of the inert ingredients not cleared by the Agency, must be provided.

FMC Response

FMC has requested the supplier of the inerts, Omnichem, to allow EPA access to the needed details concerning their inerts. The CSFs for the two Omnichem inerts

were modified, and were updated as of 10/15/01 (See Confidential Appendix).

AND

Because the proposed uses of Aim 2 EC and Aim 2 EW include food and feed uses, the inerts listed in the Confidential Appendix must be cleared for use in foods and feeds.

Current TRB Conclusion

The inerts included in the revised CSF for Aim 2 EC, dated 10/19/01, are now exempt from the requirement of a food tolerance (See Confidential Appendix).

6/12/01 Deficiency

FMC has already agreed to initiate the required Storage Stability (830.6317) and corrosion characteristics (830.6320) studies. These studies are in progress.

FMC Response

This deficiency is resolved.

OVERALL TRB CONCLUSIONS

TRB has no objection to the registration of Aim 2EC, in light of its revised 10/19/01 CSF, the corrected nominal concentration on the modified label, and the clearance of the use of the OmniChem inerts for use on foods and feeds, providing no new revisions have been made to the modified label besides those discussed in this review agreed. FMC has already agreed to initiate the required Storage stability (830.6317) and corrosion characteristics(830.6320) studies (See the Confidential Appendix for additional Conclusions).

SUBJECT: PRODUCT CHEMISTRY REVIEW OF MP ☐ EP ☒

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PRODUCT NAME: Aim 2EC

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1. Reviewer: Linda L. Kutney
2. Company: FMC Corp Agricultural Products Group
3. Type of Submission: Registration ☒ Reregistration ☐ New ☒
Resubmission ☐ Amendment ☐ "ME-TOO" ☐ Alternate Formulation ☐
Experimental Use Permit ☐ Other (Specify) _____
4. If "Me-TOO" Registration, this product is ☐ is not ☐ similar or substantially similar to EPA's Reg. No.: _____
If not, comment in Confidential Appendix A on the differences between the registered and the new source where significant

CONFIDENTIAL STATEMENT OF FORMULA

5. Type of formulation and the sources of active ingredients:
 - Non-integrated formulation system.....☒
 - Are all technical grade active ingredients used registered? • yes ☒ • no ☐ , If no, specify _____
 - Integrated formulation system.....☐
6. Clearance of intentionally added ingredients in the formulation for the intended use (indicate in the Confidential Appendix those that are not cleared; the PC Codes should be provided by the chemist on the CSF for those that are cleared):
 - 6(a) Formulation intended for food use under 40CFR§180.1001:
 - yes ☒ • no ☐ Cleared under list: • c ☐ • d ☐ • e ☐
 - Some are cleared, others are not ☐ Are there any limitations for use as an inert under 40CFR§180.1001? **ALL INERTS ARE NOW CLEARED FOR USE IN FOODS**
 - yes ☐ • no ☐ , If yes, specify _____
 - 6(b) Formulation intended for non-food use:
 - yes ☐ • no ☒ • Some are cleared, others are not ☐
 - 6(c) Clearance by the FDA of certain formulations under 21CFR§170 to 199.
Examples: (a) indirect food additives, such as food contact surface sanitizers; adhesives, coatings, paper and paperboard products that may contact food in packaging or holding; and (b) substances generally recognized as safe (GRAS).
 - yes ☐ • no ☒ • Some are cleared, others are not ☐
 - If yes, the entire formulation is cleared under 21CFR§_____
7. The density, pH, and flammability values given on the CSF are identical with those of GRN 830.7300(density), 830.7000(pH), and 830.6315(Flammability), respectively:
 - yes ☒ • no ☐

8. The nominal concentrations (NC) of the active ingredients and the upper and lower certified limits (UCL & LCL) are as follows: **(AS INDICATED ON THE 10/19/01 CSF)**

Active ingredient(s)	% by weight		
	NC	UCL	LCL
Carfentrazone-Ethyl	22.4	23.0	21.7

9. The calculated NCs, based on the pure active ingredients (PAI), are identical to those on the label:

• yes ☒ • no ☐

The label claim is now identical to the nominal concentration on the 10/19/01 CSF.

10. The certified limits are within the standard limits as per 40CFR§158.175 or are adequately explained if different: • yes ☐ • no ☒

All of the inerts are now cleared or Agency approved for use on foods (See Confidential Appendix).

PRODUCT LABEL

11. The chemical names of the active ingredients on the label are identical to those on the CSF: • yes ☒ • no ☐
12. The appropriate physical and chemical hazards statement regarding flammability or explosive characteristics of the product are given on the label:
• yes ☒ • no ☐ • not applicable ☐
13. The storage and disposal instructions for the pesticide and container are in compliance with PR Notice 84-1 for household use products or PR Notice 83-3 for all other uses:
• yes ☒ • no ☐

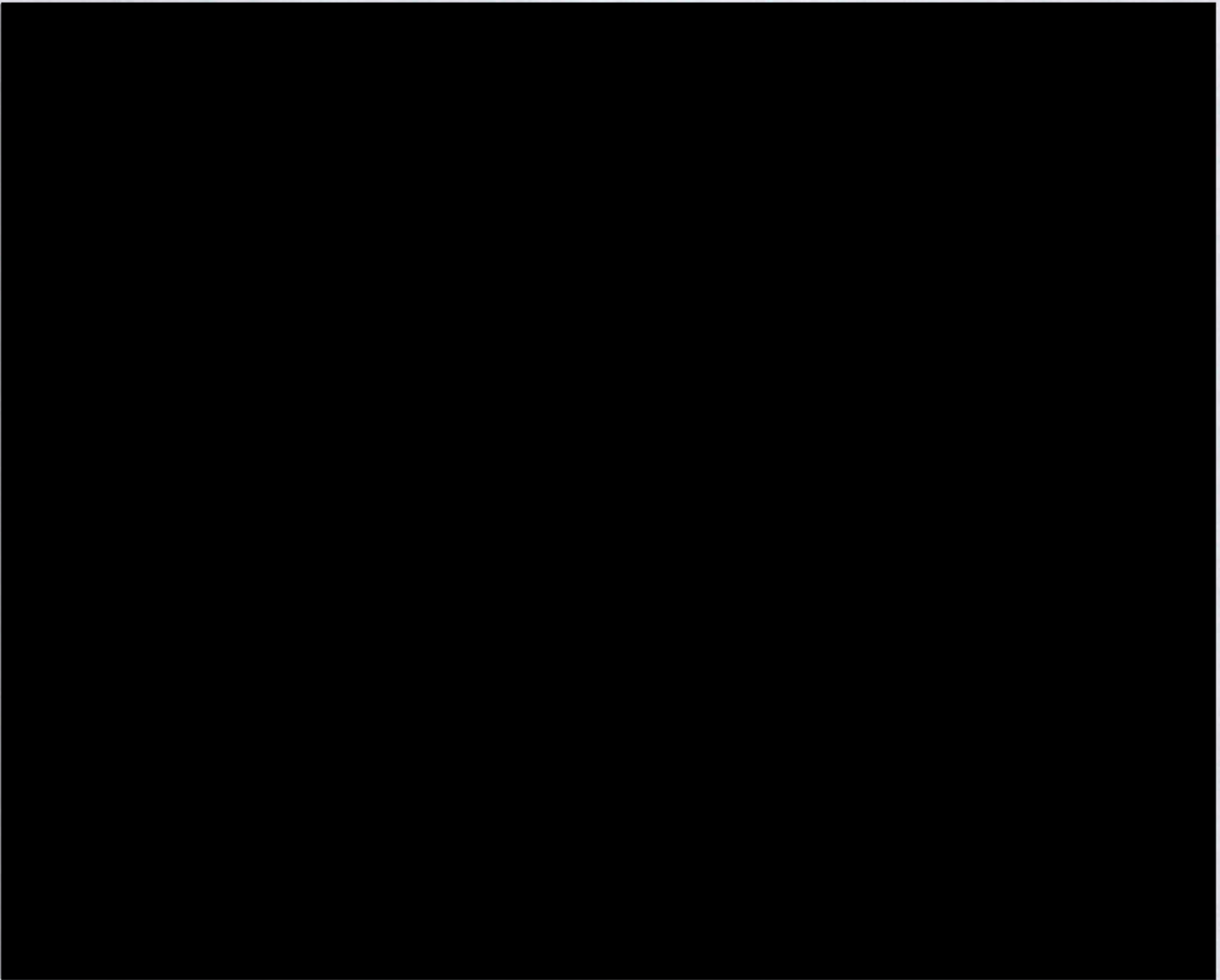
PRODUCT CHEMISTRY DATA (SERIES 830 Subgroup A & Subgroup B)

14. Chemical IDs/Manufacture/ Analytical Information New Guideline:830.--	Data Required Fulfilled	MRID No.
1550. Chemical Identity(CSF)	YES <i>Inerts are now cleared for use on pesticides, os for use on foods (See Confidential Appendix)</i>	
1600. Beginning Materials	Yes	453252-01
1620. Formulation Process	Yes	453252-01
1750. Certified Limits (CSF)	YES <i>Inerts are now cleared for use on pesticides, os for use on foods (See Confidential Appendix)</i>	
1800. Enforcement of Analytical Method (required for integrated products & those of tox. concern)	Yes	453252-01
1900. Submittal of Samples (required for integrated products, those of tox. concern, and for nonintegrated products with interference, etc, method problems)	NO. Will be required prior to Registration	

15. Physical/Chemical Properties New Guideline No. 830.---	<u>Data Required Fulfilled</u>	<u>Value or Qualitat. Descrip.</u>	<u>MRID No.</u>
6303. Physical State	Yes	Yellow- Orange Liquid @ 20 C	453252- 01
6314. Oxidation Reduction Reaction	Yes	Does not contain strong oxidizers or reducers	453252- 01
6315. Flammability/Flame Extension	Yes	>75.6 C or 168 F	453252- 01
6316. Explodability	Yes	FMC says contains no high energy ai or inert, Will not explode, but is flammable	453252- 01
6317. Storage Stability	<i>Underway</i>	Compatible for 1 month, room temperature, in paper and polyethylene	453252- 01
6319. Miscibility	Not Required	Not diluted in organic solvents	453252- 01
6320. Corrosion Characteristics	<i>Underway</i>	Compatible for 1 month, room temperature, in paper and polyethylene	453252- 01

6321. Dielectric Breakdown Voltage	Not Required	Not used around electrical equipment	453252- 01
7000. pH	Yes	4.66 @ 21.8 C	453252- 01
7100. Viscosity	Yes	8.19 Centistokes at 25 C	453252- 01
7300. Density/Bulk Density	Yes	1.075 g/ml, 8.97 lb/gal at 20 C (68 F)	453252- 01

CONFIDENTIAL APPENDIX



Inert ingredient information may be entitled to confidential treatment